

**REMARKS/ARGUMENTS**

Claims 1-10 remain in this application. Claims 4-9 have been amended to correct numbering problems, specifically related to the double numbering of claim 4. The following issues are outstanding in the Office Action dated October 28, 2003:

- Claims 1, 4, 5 (now Claim 6), and 9 (now Claim 10), were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,458,109 to Henley (hereinafter referred to as “Henley”)
- Claims 2 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of U.S. Patent No. 5,611,846 to Overton, et al. (hereinafter referred to as “Overton”)
- Claim 4 (now Claim 5) was rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of U.S. Patent 6, 017,440 to Lewis et al. (hereinafter referred to as “Lewis”).
- Claim 6 (now Claim 7) is rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of U.S. Patent No. 5,855,570 to Scherson et al. (hereinafter referred to as “Scherson”)
- Claim 7 (now Claim 8) is rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of U.S. Patent No. 6, 298,767 to Fleischmann (hereinafter referred to as “Fleischmann”)
- Claim 8 (now Claim 9) is rejected under 35 U.S.C. § 103(a) as being unpatentable over Henley in view of U.S. Patent No. 4,955,391 to Parker (hereinafter referred to as “Parker”).

Applicant respectfully traverses the rejections and objections, and in light of the following remarks requests reconsideration and withdrawal thereof.

**Claim Rejections – 35 USC §102(e): Henley**

The Examiner has rejected Claims 1, 4, 5 and 9 under 35 U.S.C. §102(e) as being anticipated by Henley. In particular, Henley is cited for teaching a wound treatment apparatus with a bandage assembly that includes a drainage bandage (20) that contacts the wound and a delivery bandage 18 that seals the drainage bandage 20 and the wound site (col. 5, lines 11-17). Further, it is contended that Henley teaches a vacuum source fluidically communicating with the drainage bandage 20 via flexible tube 24, a sensing device (172 or 174) interposed between the delivery bandage and the vacuum source, and a collection canister (164 or 166) interposed between the drainage bandage 20 and the sensing device (172 or 174, Figs. 1 and 19, and col. 13, lines 1-3).

This rejection is traversed as being improper as to Claim 1 and 4. Specifically, Henley fails to contain every element recited in the claims in as complete detail as is contained in the claim and *arranged as recited in the claim*. See M.P.E.P § 2131. In particular, Henley discloses a sensing device (172 or 174) interposed between a collection canister (164 or 166) and the control system (44), not between the delivery bandage (20) and the vacuum source (176), which is a significant difference from the invention as claimed—both in arrangement and element. See Figure 19. This is clearly evident, inasmuch as the only elements Henley shows interposed between the bandage and vacuum source are the canisters, feed valves, pressure regulator (182) and filter (184). No sensor is found interposed between the bandage and vacuum.

Claim 5 has been amended to correct improper numbering, and is now Claim 6. In addition, Claim 5 has been amended to better describe the sensing device. Henley et al. fails to

disclose a sensing device for detecting infection. Support for these amendments can be found at least in paragraph [0016] of the application as filed. As such, Claim 5 (now Claim 6) is in condition for allowance, as is dependent Claim 9 (now Claim 10).

As such, withdrawal of the rejections of Claims 1, 4, 5 (now Claim 6), and 9 (now Claim 10) is respectfully requested. No new matter has been added.

**Claim Rejections – 35 USC §103(a): Henley in view of Overton**

The Examiner has rejected Claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over Henley in view of Overton. The Examiner applied Henley in the same manner as above, except Henley does not teach that the sensing device comprises a gas chromatograph comprising a photo diode. The Examiner stated that Overton teaches a portable gas chromatograph comprising a photoionization (which contains a photo diode) detector, and concluded it was obvious to one of ordinary skill in the art at the time the invention was made to substitute the sensor of Henley for the gas chromatograph of Overton, in order to detect microorganisms in the drainage fluids.

Henley does not teach the interposition of a sensing device between the delivery bandage and vacuum source, as claimed in independent Claim 1 and stated above with respect to the 102(e) rejection. Nor does Overton teach, suggest or otherwise motivate such an interposition. One of ordinary skill would lack motivation to substitute the sensor of Overton into Henley at least for this reason.

Moreover, the combination of Overton with Henley will defeat the purpose of Henley, and fail to function. When combined with Overton, the gas chromatograph will be unable to *serve the function of the sensor* of Henley. This is particularly evident because the purpose of

the sensor of Henley is to *determine the pressure* of the collection canister. One of ordinary skill would lack motivation to look to Overton in combination with Henley to substitute a gas chromatograph into the invention of Henley. The resulting modified Henley device would fail, as there would be no way to determine the pressure of the collection canister (and thus the volume therein) to operate the valves of Henley to redirect flow, which would lead to overflow, backup and abhorrent contamination of the wound surface and other system components.

Accordingly, Claim 2 and 3 are submitted to be allowable over Henley in view of Overton. Withdrawal of the rejections is respectfully requested.

**Claim Rejections – 35 USC §103(a): Henley in view of Lewis**

The Examiner has rejected Claim 4 (now Claim 5) under USC §103(a) as being unpatentable over Henley in view of Lewis. The Examiner stated that Henley does not teach that the sensing device comprises a sensor array. The Examiner contended that Lewis teaches sensor arrays for detecting microorganisms, and concluded it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the sensor of Henley for the sensor array of Lewis in order to detect microorganisms in the drainage fluids.

This contention fails for the same reason the combination of Overton et al. with Henley fails: the resulting combination would cause flow problems within the modified device. More particularly, one of skill in the art would not look to Lewis as a substitute sensor for the pressure sensor of Henley because the combination of Lewis and Henley would cause the same problems as the combination of Overton et al. and Henley: contamination, flow blockage, overflow, and other undesirable conditions.

As such, it would not be obvious to one of skill in the art at the time the present invention was made to substitute the sensor array for detecting microorganisms of Lewis for the pressure sensor of Henley.

Accordingly, Claim 4 (now Claim 5) is submitted to be allowable over the cited art. Withdrawal of the rejection is respectfully requested. Claim 4 has been renumbered to Claim 5 due to prior improper claim numbering. No new matter has been added.

**Claim Rejections - USC §103(a): Henley in view of Scherson**

The Examiner has rejected Claim 6 (now Claim 7) as being unpatentable over Henley in view of Scherson. The Examiner noted Henley did not disclose a dressing (screen means) that is embedded with a sensing device, but that Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor. The Examiner concludes that it would have been obvious to one of skill in the art to provide the invention of Henley with a dressing embedded with a sensor in order to detect the pressure in the atmosphere at the wound area.

Scherson teaches “[a] portable, self-contained device...for the topical application of oxygen to promote the healing of skin wounds.” *Abstract*. Scherson teaches an oxygen regulator to generate oxygen according to an electrochemical process and supplies it to a skin wound. Col. 2, lines 21-29. As such, ambient air is drawn through the device at ambient pressure, and creates an enriched oxygen environment sustainable under *hyperbaric* pressure during a treatment cycle. Col. 2, lines 30-43. Without the hyperbaric pressure, the device of Scherson will be unable to create a sustainable, enriched oxygen environment, which is the very purpose of Scherson.

Substituting the invention of Scherson into the invention of Henley would defeat this purpose: creation of a sustained, oxygen-enriched environment through oxygen generation from ambient air under hyperbaric pressure. Indeed, the negative pressure supplied by Henley to drain wound surfaces would *entirely teach away* from the hyperbaric pressure teaching of Scherson for maintenance of an oxygen-rich environment. Accordingly, one of skill in the art would not think to modifying Henley by combining it with the device of Scherson, because, at the least, the two inventions teach away from each other.

Accordingly, it is respectfully submitted that the invention of Claim 6 (now Claim 7) is submitted to be allowable over the cited art. Withdrawal of the rejection is respectfully requested. Claim 6 has been renumbered to Claim 7 due to improper claim numbering. No new matter has been added.

#### **Claim Rejections - USC §103(a): Henley in view of Fleischmann**

The Examiner has rejected Claim 7 (now Claim 8) as being unpatentable over Henley in view of Fleischmann. The Examiner noted Henley did not teach the sensing device as being disposed on sealing means. The Examiner found Fleischmann as teaching a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means (fig. 1 and col. 4, lines 62-64). The Examiner concluded that it would have been obvious to provide the sealing means of Henley with a sensing device to detect the pressure in the atmosphere near the wound area.

Independent Claim 6, upon which the present claim depends, has been amended to clarify the function of the sensing device for detecting infection, which neither the sensor Fleischmann nor the sensor of Henley is capable of performing. In addition, Fleischmann utilizes *positive*

*pressure* to supply active substances to a wound surface (see Abstract, col. 4, line 66) and

*negative* pressure to remove the substances, whereas Henley only utilizes *negative pressure* to remove substances from a wound surface. One of skill in the art would not be motivated, taught or suggested to combine the *pressure sensor* of Fleishmann with the *pressure sensor* of Henley to arrive at an *infection-detecting sensing device* of the present invention.

Accordingly, Claim 7 (now Claim 8) is submitted to be allowable in view of the cited references. Withdrawal of the rejection is respectfully requested. Claim 7 has been renumbered due to improper claim numbering. No new matter has been added.

### **Claim Rejections – USC §103(a): Henley in view of Parker**

The Examiner has rejected Claim 8 as being unpatentable over Henley in view of Parker. The Examiner stated Henley does not disclose a sensing device located in the canister. The Examiner contended it is well known in the art that canisters are used as collection devices for fluids, and thus the fluids can be assessed. The Examiner further contended Parker teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col. 4, lines 16-21). The Examiner concluded it would have been obvious to modify the location of the sensing device from being placed outside the canister to being placed within the canister for more accurate sensing of pressure within the canister.

Henley lacks an infection-detecting sensing device, and only includes a sensor to monitor pressure of the collection canister to prevent overflow, backflow, contamination, and other flow problems. Parker, likewise, neither teaches, suggests, nor discloses such an infection-detecting sensing device, much less one disposed with the canister.

Accordingly, one of skill in the art would not be taught, suggested or motivated to combine the teaching of Parker by introducing a *pressure sensor* within the canister of Henley. Such a combination would inherently lead to problems resulting from worn pressure seals that would have to be continuously replaced in order to maintain a hermetic, clean environment.

Accordingly, Claim 8 (now Claim 9) is submitted to be allowable over the cited art. Withdrawal of the rejection is respectfully requested. Claim 8 has been renumbered to Claim 9 to correct improper claim numbering. No new matter has been added.

**SUMMARY**

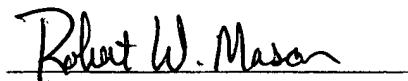
Believing it has addressed all matters raised by the Examiner's November 19, 2003 Office Action, Applicants respectfully request timely action on the merits. No fees are believed to be required for the amendment. Nevertheless, the Commissioner is permitted to deduct or credit any fees that may be required from Kinetic Concepts Inc. Deposit Account No. 500-326.

In view of the above, it is submitted that the claims are now in condition for allowance. Reconsideration and withdrawal of the rejections is hereby respectfully requested. Allowance of Claims 1-10 at an early date is solicited.

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

Applicant respectfully requests favorable consideration.

Respectfully submitted,

  
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